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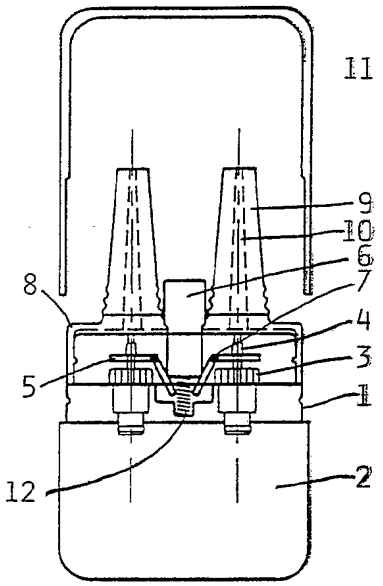
(54) Title: NASAL DISPENSER ACTUATED BY NOSE CONTACT

(57) Abstract

A dispenser for intranasal administration of one or several biologically active substances comprises a vessel (2) containing a pressurized propellant, at least one duct (10) connecting a nosepiece (9) with the vessel (2), and a valve (3) closing the passage from the vessel (2) to the nosepiece (9). The valve (3) has means (6) opening this valve (3) by nose contact when the nosepiece (9) is inserted in a nostril. The biologically active substance is placed in the duct (10) and is entrained by the propellant out through the nosepiece (9) and into the nostril when the valve (3) is activated by nose contact with the opening means (6). Preferably, two nosepieces are provided so that nosepieces may be concomitantly inserted in both nostrils, and the valve opening means (6) is placed between the two nosepieces to be activated by the septum of the nostrils when the nosepieces are inserted.



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NASAL DISPENSER ACTUATED BY NOSE CONTACT

The invention relates to a dispenser for intranasal administration of biologically active substances, hereafter designated as medicine doses. The dispenser is usable at mammalians including humans, in the following designated as patients.

Many illnesses, e.g. diabetes or epilepsy, have the result that the patient may suddenly feel indisposed or even faint. Such cases of indisposition may be remedied by quickly giving a medicine to the patient, e.g. glucagon to a hypoglycaemic diabetic or diazepam to an epileptic having an attack. Such medicine may be given by injection, but a nasal administration is preferred as it will often be an untrained person who has to help the patient.

For this use the patient himself may carry an emergency device by which a dosis of medicine may quickly be administered. A device is known by which the air in a vessel may be comprimated whereafter a nosepiece is inserted into a nostril and a manual trigger button is actuated to release the air from the vessel through the nosepiece. By actuating the trigger an aluminum membrane at each end of a cartridge is perforated and the air is led through this cartridge on its way to the nosepiece.

Such apparatus is well usable for a patient who feels indisposed and knows that the medicine must be taken, but it is less suited as a first aid device which has to be handled by incidental people helping a patient who has fainted.

The object of the invention is to provide a dispenser which needs only little or no instruction for use, is easy to use, and fast to handle.

This may be obtained by a dispenser comprising one or two nosepieces and being actuated by nose contact when the nosepiece or the nosepieces are inserted into a nostril or the nostrils of a mammal, e.g. a human patient.

According to the invention, the dispenser may further comprise a vessel containing a pressurized propellant, e.g. atmospheric air, at least one duct connecting the nosepiece or the nosepieces with the vessel, at least one valve closing the passage from the vessel to the nosepiece or the nosepieces, and means for open-

ing the valve by nose contact, the biolocical active substance being contained in the propellant or in the passage from the vessel to a nostril of the patient to be entrained with the propellant into his nose cavity when the valve or the valves are opened.

This dispenser is easy to use for an untrained person as all he has to do is to insert the nosepiece or the nosepieces into a nostril or the nostrils of a patient. When the nosepiece or the nosepieces are fully inserted the valves will be actuated and the propellant will be released to flow through the ducts and the nosepieces into the nose cavity of the patient, entraining the medicine placed in the passage for the propellant.

To make sure that the the propellant is expelled quickly by a velocity securing the entraining of the medicine the valve may be of a bistable type being closed but turning to fully opened when activated.

According to the invention, the nosepiece or the nosepieces may be flexible to adapt themselves to the nose of the patient. The nosepieces may easily be forced away from each other or towards each other in accordance with the distance between the nostrils, and each nosepiece may be telescoped into itself to make sure that the valve or the valves may be activated from patients with short nostrils.

The medicine may be a liquid placed in the duct or the nosepiece or it may appear as a solid in the form of a powder and/or as a suspension placed in the duct and/or the nosepiece, and a solvent may be a part of the propellant or be placed in this duct or nosepiece upstream in relation to the powder or the suspension and be separated from this powder or suspension.

An incidental person may not know if one of the patient's nostrils is stopped, and, therefore, it is preferred that the dispenser has two nosepieces to make sure that the patient gets the needed medicine. Besides, the absorbing surface may be increased in this vay.

Acording to a further development, each nosepiece may have its own independent duct and valve, the valves being designed to open simultaneously to omit that all the propellant is released through one valve before the other opens. Another way to omit such an uneven distribution of the propellant flowing through

the two nosepieces may be to divide the vessel into two compartments each supplying its own independent duct, valve and nosepiece.

In a preferred embodiment having two nosepieces the valve or the valves are actuated by actuating means abutting the lower edge of the septum of the nostrils.

Although the dispenser may be designed to be reloaded with propellant and medicine, a disposable device is preferred. The device may be designed to change its appearance irreversibly when used e.g. by having a cover which cannot be replaced when it has been removed. The dispenser may be worn as an emergency kit which possibly will not be used at all during its lifetime. When used it may be disposed of and its change of appearance by use will make it evident that the device will no longer function and has to be replaced by a new one.

The medicine dose may be contained directly in the duct or the nosepiece or it may be contained in a capillary or in a cartridge inserted in the duct or the nosepiece. The volume of the dose may be of the order 0,1μl - 50ml, more preferred is 1 - 300μl, and most preferred is 25 - 125μl.

The invention will now be described in further details with reference to the drawing in which

Fig. 1 shows schematically an embodiment of a dispenser according to the invention,

Fig. 2 shows the dispenser of Fig. 1 in its released condition,

Fig. 3 shows another embodiment with a common valve for two nosepieces.

The dispenser in Fig. 1 comprises a housing 1 having a vessel 2 for containing a pressurized propellant, e.g. air under a superatmospheric pressure. In the upper wall of the vessel 2 a pair of valves 3 are mounted. These valves may be of the kind known from cigarette lighters having a hollow stem 4 which when lifted opens the valve for a flow through the central bore of the stem.

A lever 5 is at its one end gripping under a thickening on the stem 4 to lift this stem when its other end is actuated by the lower end of a button 6, the lever being about its middle mounted rotatably on a pin 7 dividing it into two arms.

On the top of the housing 1 a cover 8 is mounted having two nosepieces 9 each having an axial duct 10 containing a medicine dose to be dispensed. The medicine is confined in the ducts which at their bottom may be closed by a pierceable membrane and at their top may be closed by not shown stoppers which may be carried by a removable lid 11 covering the nosepieces when the device is not in use.

The button 6 is situated between the nosepieces 9 at the lower end thereof. The lower end of the button 6 faces an end of each of the levers 5, but is held out of engagement with these levers by a spring 12 pressing the button 6 upwards.

When the device is to be used the lid 11 is removed and thereby not shown stoppers carried by the lid are removed from the free ends of the nosepieces 9. The nosepieces are now passed into the nostrils of a patient until the septum of the nostrils abuts the upper end of the button 6. By further insertion of the nosepieces 9 the button 6 will be pressed down by the septum against the force of the spring 12 and its lower end will actuate one end of the respective levers 5 making the other ends lift the stems 4 of the respective valves releasing the pressurized propellant in the vessel 2 through these valves.

When the stems 4 of the valves are lifted they will perforate the membranes at the bottom of the ducts 10 of the nosepieces, thereby ensuring that the released propellant will flow through these ducts and entrain the medicine in the ducts into the nostrils of the patient.

After use the device may be disposed of and to make it easy to see that the device is no longer usable provisions may be made to make it change its appearance irreversibly when it has been used. This may be done by making it impossible to replace the lid on a used device.

Fig. 3 shows a sectional view of another embodiment of the device. In this embodiment the two nosepieces are supplied with propellant through one common valve 3 which is opened in a not further specified way when the button 6 is pressed down by the septum of the nostrils when the nosepieces are passed into the nostrils of the patient. In this embodiment, it is further shown that the medicine

doses are contained in capillary tubes 13 extending through the ducts in the nosepieces.

Although the shown embodiments have two nosepieces, devices having only one nosepiece, but with means for automatic release when the nosepiece is fully inserted in the nostril, are considered within the scope of the invention.

The same considerations go for embodiments where the device is not a disposable one, but may be reloaded with propellant and medicine. A metered dose device for repeated dosing wherein the medicine e.g. is dissolved or suspended in the propellant possibly together with a cosolvens is also considered within the scope of the invention.

CLAIMS

1. A dispenser for intranasal administration of one or several biologically active substances, e.g. medicine doses, **characterized** in that it comprises one or two nosepieces and is actuated by nose contact when the nosepiece or the nosepieces are inserted into a nostril or the nostrils of a mammal, e.g. a human patient.

2. A dispenser according to claim 1, **characterized** in that it further comprises a vessel containing a pressurized propellant, e.g. atmospheric air, at least one duct connecting the nosepiece or the nosepieces with the vessel, at least one valve closing the passage from the vessel to the nosepiece or the nosepieces, and means for opening the valve by nose contact, the biolocical active substance being contained in the propellant or in the passage from the vessel to a nostril of the mammal.

3. A dispenser according to claim 2, **characterized** in that the valve or the valves are of a bistable type being closed but turning to fully opened when actuated.

4. A dispenser according to any of the preceding claims, **characterized** in that the nosepiece or the nosepieces are flexible to adapt themselves to the nose of the patient.

5. A dispenser according to any of the preceding claims, **characterized** in, that the biologically active substances are liquid or dissolved and placed in the duct or the nosepiece.

6. A dispenser according to any of the preceding claims, **characterized** in that the biologically active substances appear as a solid in the form of a powder and/or as a suspension placed in the duct and/or the nosepiece, and that a solvent is a part of the propellant or is placed in this duct or nosepiece upstream in relation to the powder or the suspension and is separated from this powder or suspension.

7. A dispenser according to any of the preceding claims, **characterized** in, that it has two nosepieces.

8. A dispenser according to claim 7, **characterized** in that the nosepieces each has its own independent duct and valve, the valves being designed to open simultaneously.

9. A dispenser according to claim 7, **characterized** in that the vessel is divided into two compartments each supplying its own independent duct, valve, and nosepiece.

10. A dispenser according to claim 7, 8 or 9, **characterized** in that the valve or the valves are actuated by actuating means abutting the edge of the septum of the nostrils.

11. A dispenser according to any of the preceding claims, **characterized** in that it is designed as a disposable device.

12. A dispenser according to claim 11, **characterized** in that it is designed to irreversably change its appearance when used.

13. A dispenser according to claim 12, **characterized** in that it is provided with a cover which cannot be replaced when removed.

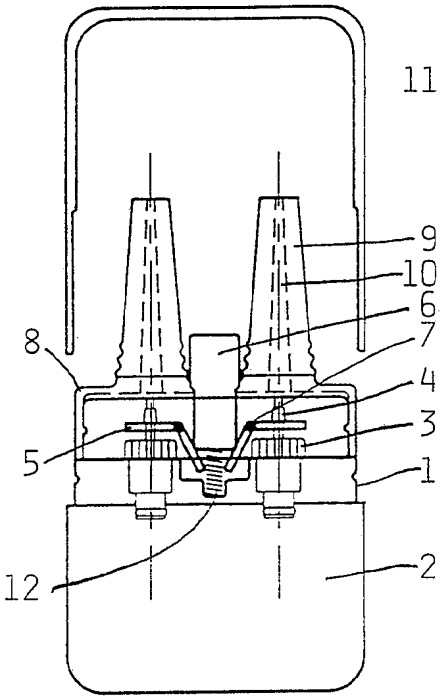

Fig. 1

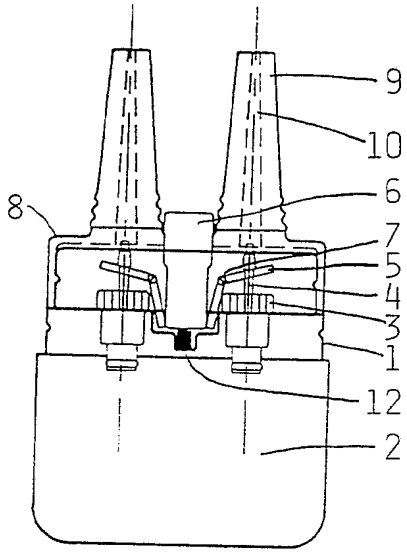

Fig. 2

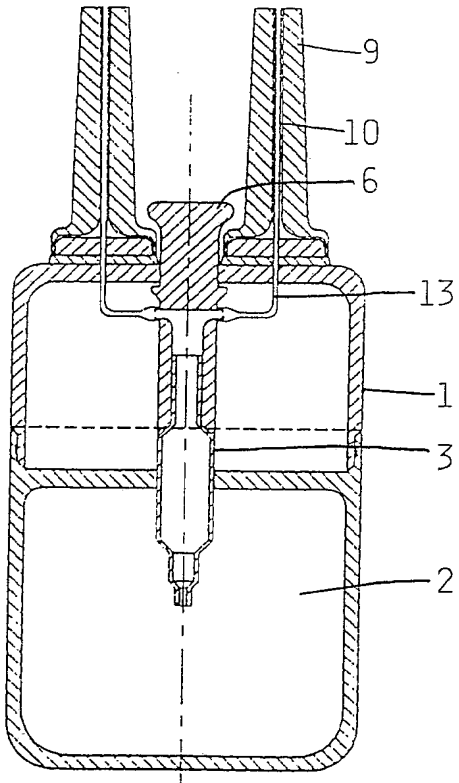

Fig. 3

INTERNATIONAL SEARCH REPORT

International Application No PCT/DK 92/00169

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC5: A 61 M 11/02, 15/08

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
IPC5	A 61 M

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in Fields Searched[8]

SE,DK,FI,NO classes as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category *	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
A	EP, A1, 0452728 (COSTER TECNOLOGIE SPECIALI S.P.A.) 23 October 1991, see column 9, line 18 - line 45; figures 15,16 --	1
A	US, A, 2052321 (H.V. SMART) 25 August 1936, see page 2, line 33 - line 51; figure 4 --	1
A	US, A, 3269389 (B.L. MEURER ET AL) 30 August 1966, see column 1, line 48 - line 57; figures 2,3 --	1

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* **Special categories of cited documents:** [10]

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
11th September 1992	1992 -09- 15
International Searching Authority	**Signature of Authorized Officer**
SWEDISH PATENT OFFICE	Lena Nilsson

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. PCT/DK 92/00169

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A1- 0452728	91-10-23	DE-A- 4016126	91-10-24
US-A- 2052321	36-08-25	NONE	
US-A- 3269389	66-08-30	NONE	